UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 2666 (JNE/FLN)
This Document Relates to **ALL ACTIONS**	

DEFENDANTS' MEMORANDUM IN RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF SAMSUN LAMPOTANG, PH.D.

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INTRODUCTION

Plaintiffs' motion to exclude the opinions and testimony of defense expert Dr. Lampotang should be denied. Dr. Lampotang is a professor of anesthesiology and biomedical engineering, with a Ph.D. in mechanical engineering. He has 35 years of experience in the anesthesia environment, and has been retained as a rebuttal expert by Defendants to offer opinions regarding the safety and efficacy of the Bair Hugger patient warming system. Dr. Lampotang concluded that Defendants acted reasonably in the design, testing, research, and development of the Bair Hugger and, based on the available, credible, scientific literature, there is no evidence that the design of the Bair Hugger causes, is a substantial factor in causing, or increases the risk of, surgical site infections.

Plaintiffs' motion to exclude Dr. Lampotang is premised on mischaracterizations of both his testimony and the case law regarding rebuttal experts. For example, Plaintiffs insist that at certain times during his deposition, Dr. Lampotang could not recall certain details of a document, and that his lack of recollection also demonstrated a lack of intellectual rigor. This is not true. The deposition testimony shows that Plaintiffs' counsel never introduced the document at issue as an exhibit to refresh Dr. Lampotang's memory, even after Dr. Lampotang stated he could provide clarification if shown the document. (Declaration of Benjamin W. Hulse in Support of Defendants' Memorandum in Response to Plaintiffs' Motion to Exclude the Expert Opinions and Testimony of Samsun

Lampotang, Ph.D. ("Hulse Decl."), DX1, Dep. Trans. of Samsun Lampotang, Ph.D. ("Lampotang Dep."), dated Aug. 11, 2017, at 184:1-9.)[1]

Plaintiffs also argue that Dr. Lampotang's critique of Plaintiffs' experts or published studies are just inadmissible statements that contain no expert gloss. As discussed below, this Court has recognized that rebuttal experts can testify to the flaws that he or she believes are inherent in another expert's reports. *See Aviva Sports, Inc. v. Fingerhut Direct Marketing, Inc.*, 829 F. Supp. 2d 802, 835 (D. Minn. 2010). Dr. Lampotang provides support for his rebuttal of Plaintiffs' experts' opinions.

For these reasons, and additional reasons below, this Court should deny Plaintiffs' motion in its entirety, and allow Dr. Lampotang to present his opinions at trial.

DR. LAMPOTANG'S BACKGROUND

I. DR. LAMPOTANG'S QUALIFICATIONS.

Dr. Lampotang is a Professor of Anesthesiology and an Affiliate Professor of Biomedical Engineering at the University of Florida (UF). (DX2, Report of Samsun Lampotang, Ph.D. ("Lampotang Rept."), June 2, 2017, ECF No. 746-1 at 2.) He earned his Ph.D. in Mechanical Engineering from UF in 1992, with a concentration in thermal sciences (heat transfer: conduction, convection and radiation, fluid mechanics, thermodynamics, mathematics). (*Id*.) For the past 35 years, Dr. Lampotang has worked in an anesthesia environment on a daily basis. (*Id*.) Since 1992, he has taught residents and practicing anesthesiologists how to safely use anesthesia machines. (*Id*.) He has

[1] Cites to "DX" are exhibits to the Declaration of Benjamin W. Hulse filed concurrently with this response.

designed, built, and evaluated an electronically-controlled anesthesia machine. (*Id*.) Dr. Lampotang is also a co-inventor of several other medical devices: a blood/fluid warmer to help maintain normothermia; cooling football pads for the prevention of heat stroke; and a Peltier heat exchanger for use during anesthesia featuring a closed circuit anesthesia machine to preserve heat and humidity. (*Id* at 2-3.)[2]

With respect to infection prevention, Dr. Lampotang was the principal investigator on a research grant awarded to UF by CareFusion, the manufacturer of the ChloraPrep, a chlorhexidine-based skin preparation applicator. (*Id*. at 2-3.) UF designed a screen-based simulator for learning how to prepare and disinfect the skin prior to surgical incision. (*Id.*; DX1, Lampotang Dep. at 117:19-118:7.) Dr. Lampotang also helped develop a screen-based simulation for anesthesiologists on how to dose and how to time the administration of cefazolin (trade name Ancef), an antibiotic that is administered prophylactically, to prevent a number of bacterial infections, before surgical incision and then subsequently re-dosed during prolonged surgery. (DX2, Lampotang Rept. at 3; DX1, Lampotang Dep. at 118:9-120:6.)

During his 35 years of research, teaching, and work in the anesthesia environment, Dr. Lampotang has become very familiar with patient warming systems, including the Bair Hugger patient warming system. (DX2, Lampotang Rept. at 4.) The Bair Hugger is used at the UF Academic Health Center where Dr. Lampotang teaches. (*Id*.) He has seen the

[2] Dr. Lampotang's extensive qualifications are fully described in his CV, which Plaintiffs have not included as an exhibit. It is included as an exhibit (DX2) to Defendants' Declaration of Benjamin W. Hulse.

Bair Hugger system used during multiple surgical procedures. (DX1, Lampotang Dep. at 198:13-25.) Thus, Dr. Lampotang is well qualified to offer his opinions and testimony regarding the design of the Bair Hugger patient warming system, the prevention of infections in the operating room, and how the design of the Bair Hugger system may play a role in preventing infections during use in the operating room.

II. DR. LAMPOTANG'S METHODOLOGY.

Dr. Lampotang conducted a literature search. (DX2, Lampotang Rept. at 4.) He reviewed and analyzed certain relevant reports of Plaintiffs' experts, the relevant deposition transcripts of Defendants' witnesses and experts, and reviewed other materials relevant to the use of forced-air warming devices such as the Bair Hugger during surgery, including any associated risks of surgical site infections. (*Id*.) Given Dr. Lampotang's engineering expertise and experience with the Bair Hugger in the operating room, Defendants requested Dr. Lampotang to offer his opinions regarding the design and safety of the Bair Hugger system.

ARGUMENT

I. PLAINTIFFS' ATTACKS ON DR. LAMPOTANG'S QUALIFICATIONS AND METHODOLOGY ARE WITHOUT MERIT.

As an initial matter, Plaintiffs contend that Dr. Lampotang does not have the required expertise and is not qualified to offer his opinions and testimony in this litigation because, among other things, he has not done any testing related to this MDL, and he admitted to deferring to other experts on microbiology, orthopedic issues, infectious diseases, and computational fluid dynamics. (ECF No. 744 at 8-9.) It is well settled that

an expert does not have to conduct testing in order to provide relevant and reliable opinions. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). The Court in *Kumho Tire Co.* emphasized that the Daubert analysis is a "flexible one," and that an expert's opinion may be based on "professional studies or personal experience." *Id*. at 150, 152; *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239 (5th Cir. 2002) (reversing the district's exclusion of the testimony of an infectious disease doctor who conducted a literature search).

It is also well settled that an expert may rely on the opinions and testimony of other experts in fields in which they lack expertise. *See* Fed. R. Evid. 703 (2017). Facts and data upon which an expert may rely in reaching an expert opinion include the opinions and findings of other experts, if experts in their respective field would reasonably rely on other experts' opinions and findings. *Id*; *see also Monsanto Co. v. David*, 516 F.3d 1009, 1015-16 (Fed. Cir. 2008) (affirming admission of expert testimony where expert relied on "scientific reports prepared by his team"); *Ratliff v. Schiber Truck Co.*, 150 F.3d 949, 955 (8th Cir. 1998) (permitting accident reconstructionist to rely on police officer's report because it was "of the type reasonably relied upon by accident reconstructionists in forming their opinions.").

Dr. Lampotang is a mechanical engineer who has designed electrical equipment for surgical rooms, and designs simulations in order to teach medical residents proper infection prevention protocols. *See* DX2, Lampotang Rept. at 2; *In re National Hockey League Players' Concussion Injury Litigation*, MDL No. 14-2551(SRN/BRT), 2017 WL 3142399, n. 9 (D. Minn. July 25, 2017) (allowing multiple defense experts to address similar topics and subject matters because each experts' unique area of expertise and approach to the

issue does not render their opinion cumulative). It is within this unique framework that Dr. Lampotang approached the issue of evaluating whether the Bair Hugger system increased the risk of surgical site infections during surgery, and offered his opinions. As such, Dr. Lampotang's methodology included reviewing other expert reports, deposition testimony of certain witnesses, and other materials, including produced documents and published studies. (DX2, Lampotang Rept. at 4.) "Trained experts commonly extrapolate from existing data." *Huggins v. Stryker Corp.*, 932 F. Supp. 2d 972, 993 (D. Minn. 2013) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Based on Dr. Lampotang's review of the scientific literature, internal 3M Company documents, and MDL deposition testimony, he offered several opinions in support of Defendants' contention that the Bair Hugger does not cause surgical site infections: (1) the Bair Hugger warming unit is safe and efficacious; (2) Arizant and 3M acted reasonably in designing, developing, and marketing the Bair Hugger; (3) the Bair Hugger does not contaminate the surgical field; (4) the Bair Hugger filter is effective at trapping Acinetobacter *baumannii*; (5) there is no indication that surgical site infections are caused by the Bair Hugger; and (6) there are numerous potential causes/risk factors of surgical site infections. (DX2, Lampotang Rept. at 4-9, 15.)

Plaintiffs also argue that Dr. Lampotang's list of materials considered is incomplete, and therefore his opinions are rendered methodologically unsound. (ECF No. 744 at 9-10.) Plaintiffs refer to Dr. Lampotang's deposition where he testified that he reviewed the eight published studies on which Plaintiffs' rely, but they are not included on his list of

materials considered. (DX1, Lampotang Dep. at 159:15-165:3.) Dr. Lampotang also testified that he did not review the depositions of the study authors. (*Id*.)

The absence of these materials on Dr. Lampotang's list of materials considered does not render his opinions inadmissible. Plaintiffs' counsel had the opportunity to cross-examine Dr. Lampotang regarding his review of these studies during his deposition, and did not do so. Moreover, Dr. Lampotang did consider evidence relevant to this MDL. *See, e.g., Hitkansut LLC v. United States*, 127 Fed. Cl. 101, 113-14 (2016) (determining that expert's reference to the documents in his deposition but not listed in his report was harmless, and thus, sanctions were not warranted).

Moreover, a district court must keep in mind that conclusions and methodology are not completely distinct from one another. *Gen. Elec. Co*, 522 U.S. at 146. Dr. Lampotang ultimately concludes that the Bair Hugger is a safe and efficacious medical device. (DX2, Lampotang Rept. at 15.) The eight published studies Plaintiffs rely upon to support their opinion that the Bair Hugger increases the risk of infections expressly disclaim a causal connection between Bair Hugger use and surgical site infections. (Defs.' Mem. in Opp'n to Pls.' Mot. for Leave to Am. Master Long Form and Short Form Compls. to Add Cl. for Punitive Damages, May 11, 2017, ECF No. 436 at 11-16.) Thus, Dr. Lampotang's opinions and testimony are consistent with the published literature.

II. DR. LAMPOTANG'S OPINIONS ARE RELEVANT AND RELIABLE, AND THEREBY ADMISSIBLE.

A. Dr. Lampotang's Opinions that the Bair Hugger Warming Unit Is a Safe and Efficacious Medical Device, and that Defendants Acted Reasonably in Designing, Developing, and Marketing the Bair Hugger, Are Admissible.

Plaintiffs argue that Dr. Lampotang's opinions should be excluded because he does not include citations to support his opinions and his vague recollection during his deposition demonstrate a lack of intellectual rigor. (ECF No. 744 at 12-14.) Plaintiffs also contend that because Dr. Lampotang could not recall that there were no clinical trials involved in the Bair Hugger's FDA clearance, his opinion is unreliable. (*Id.* at 12.) Plaintiffs mischaracterize Dr. Lampotang's deposition testimony. In support of his opinions, Dr. Lampotang testified that he reviewed the Bair Hugger 510(k), the Design History File, and the effectiveness of the Bair Hugger filter, and that he was not aware of a case that directly linked the Bair Hugger as the cause of an infection. (DX1, Lampotang Dep. at 213:10-215:19; 238:6.) Dr. Lampotang begins by briefly mentioning clinical trials, as set-up to a discussion of the FDA's post-marketing surveillance requirements. Dr. Lampotang never intended to, or actually did, offer testimony regarding clinical trials associated with the Bair Hugger:

> A. Yes. Because when you have a – a new device you look – initially you do your Phase I, Phase II, Phase III clinical trials.
>
> Q. You understand there were no clinical trials in this; correct?
>
> A. Well I was trying to explain another basis for saying it's safe.
>
> And then after the clinical trials are over you get into what's called post-market surveillance where we look at how does this product, after the clinical trials, so you're right, behave when used over

> time. And the Bair Hugger has a long track record of being safe. There were – There is that incident with Moon where there was a fire.
>
> Q. So I'm going to – I'm going to stop you there because to the extent that you have started your answer by saying anything about clinical trials, you do understand there were no clinical trials with respect to the Bair Hugger; correct?
>
> A. I don't – I don't – I don't recall one way or another.
>
> Q. All right.
>
> A. I mentioned clinical trials as an example to set up the post-surveillance context.

(DX1, Lampotang Dep. at 214:4-215:2.)

B. Dr. Lampotang's Discussion of the Bair Hugger Filter Media MERV Rating.

Plaintiffs contend that Dr. Lampotang discusses the Minimum Efficiency Reporting Value (MERV) rating (used to rate the effectiveness of air filters) of the Bair Hugger filter media without a reference. (ECF No. 744 at 14.) Plaintiffs also imply that the MERV 14 recommendation for general surgery is unsupported and something Dr. Lampotang made up. (*Id.*) Plaintiffs also state that Dr. Lampotang makes a vague reference to testing that may have been done by Winston Tan, but is not on his list of material reviewed. (*Id.*) Plaintiffs have failed to carefully review Dr. Lampotang's list of materials considered. (ECF No. 746-2 at 2-3.) On his list is a reference to three ASHRAE standards that contain the recommended MERV ratings for filters in healthcare facilities, including general surgery operating rooms. (ECF No. 746-2 at 3.)

Additionally, the test report containing the conclusions of the filter media testing conducted by 3M employee Winston Tan is contained on the second page of Dr. Lampotang's list of materials considered, Bates number 3MBH01958789. (ECF No. 746-2 at 2.) The first page of the test report states the document owner is Winston Tan. *See* 3MBH01958789. The test report also references the ASHRAE standard followed to test the filter efficiency of the media. *See* 3MBH01958793. Plaintiffs also contend that not only did Dr. Lampotang vaguely refer to tests conducted by Winston Tan, but that Dr. Lampotang failed to review the deposition of Winston Tan. (ECF No. 744 at 14.) However, as Plaintiffs learned through discovery, the filter media used in the Bair Hugger is manufactured by supplier Pentair. Dr. Lampotang did review the deposition transcript of Pentair's Fed. R. Civ. P. 30(b)(6) witness, Robert Crowder. (ECF No. 746-2 at 1.)

C. Dr. Lampotang's Review of the Avidan et al.[3] and Bernards et al.[4] Studies.

Plaintiffs assert that Dr. Lampotang's opinion that the Bair Hugger does not contaminate the surgical field briefly mentions the Avidan et al. and Bernards et al. studies, but does not provide the expert gloss necessary to support his opinion. (ECF No. 744 at 14-15.) Plaintiffs also argue that since the filter was not mentioned by the authors of Bernards et al., Dr. Lampotang incorrectly interprets the study. (*Id*. at 15-16.) Plaintiffs are both incorrect about the study and mischaracterize Dr. Lampotang's opinion. Dr.

[3] Avidan, M.S., et al., "Convection warmers – not just hot air." Anesthesia 52 (1997). (*See* Corrected Decl. of Peter J. Goss in Supp. of Defs.' Mot. to Exclude the Opinions and Testimony of Pls.' Engineering Experts, "Goss Decl.," DX64, ECF No. 865 at 9.)

[4] *See* DX3, Bernards A.T., et al., "Persistent Acinetobacter baumannii? Look inside your medical equipment." Infection Control & Hospital Epidemiology 25.11 (2004).

Lampotang completes a very thorough review of Bernards et al. from an engineering perspective. (DX2, Lampotang Rept. at 6-7.) Since every Bair Hugger system contains a filter, Dr. Lampotang offers his engineering opinion on how the filter had to have been operating effectively in order for the Acinetobacter *baumannii* (AB) outbreak to be contained. Based on his personal experience and reading of Bernards et al., Dr. Lampotang offers a rebuttal to Plaintiffs' experts' Yadin David and Dr. William Jarvis. (*Id*. at 7.) It is Dr. Lampotang's opinion that the interior of the Bair Hugger did not harbor the infectious organism (AB), and that the Bair Hugger filter was operating effectively because after the filter was changed the outbreak stopped. (*Id*.) Had the filter of the Bair Hugger allowed the passage of AB, then the interior of the Bair Hugger, downstream of the filter, would have also harbored AB. (*Id*.) Because Dr. Lampotang offers a thorough explanation of how he reached his conclusion based on his personal experience and the data provided in Bernards' study, and his opinion critiques that of Plaintiffs' experts, his expert opinion should be allowed. *See Aviva Sports,* 829 F. Supp. 2d at 835.

A similar argument can be made for Dr. Lampotang's inclusion of Avidan et al. in his report. (DX2, Lampotang Rept. at 6.) Plaintiffs' contend that Avidan et al. demonstrates that bacteria have been found to exit the Bair Hugger hose. (ECF No. 744 at 14-15.) However, Dr. Lampotang offers Avidan et al. in support of his opinion that the Bair Hugger does not contaminate the surgical field because no air coming from Bair Hugger blankets cultured organisms in the study. (DX2, Lampotang Rept. at 6.) Utilizing his vast experience in anesthesia environments, Dr. Lampotang is able to recognize that when used properly in its intended environment, that is, with the hose attached to the

blanket, Avidan et al. demonstrates no bacterial growth. "Contrary to [P]laintiffs' suggestion, a rebuttal expert who critiques another expert's theories or conclusions need not offer his own independent theories or conclusions (though of course his testimony may be more persuasive if he does so)." *Aviva Sports*, 829 F. Supp. 2d at 835 (quoting *In re Cessna 208 Series Aircraft Products Liability Litigation*, MDL No. 1721, 2009 WL 1649773, at *1 (D. Kan. June 9, 2009)).

Plaintiffs also argue that Dr. Lampotang failed to consider the other studies cited by Plaintiffs' experts. They are wrong, as Dr. Lampotang reviewed the studies involving the Bair Hugger system on which Plaintiffs rely. (DX1, Lampotang Dep. at 159:15-162:3.) As previously stated, the eight published studies Plaintiffs rely on to support their claim that the Bair Hugger increases the risk of infections expressly disclaim a causal connection between Bair Hugger use and surgical site infections. (ECF No. 436 at 11-16.) Furthermore, Dr. Lampotang's opinion that there is no evidence that the Bair Hugger causes or increases the risk of surgical site infections is "generally accepted" by independent medical authorities such as the ECRI Institute and Association of periOperative Registered Nurses (AORN). (*See* Defs.' Mem. in Supp. of Summ. J. with Respect to General Causation, Sept. 12, 2017, ECF No. 762 at 6.) Additionally, Plaintiffs do not provide any authority which requires a rebuttal expert to consider studies cited by all of Plaintiffs' experts. The *Daubert* analysis requires that expert testimony is sufficiently tied to the facts of the case or that the expert testimony has "fit." *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1055 (8th Cir. 2000) (explaining *Daubert's* requirement of "fit"). Taken together, all of the studies, including the eight studies that Plaintiffs'

experts rely on, demonstrate that the Bair Hugger does not contaminate the surgical field. Thus, Dr. Lampotang's opinions "fit" the particular facts of this MDL. *See id*.

D. Dr. Lampotang's Opinion that There Is No Indication that Surgical Site Infections Are Caused by the Bair Hugger.

Plaintiffs argue that Dr. Lampotang's opinion that there is no indication that surgical site infections are caused by the Bair Hugger is irrelevant because the issue is whether the Bair Hugger increases the risk of prosthetic joint infections. (ECF No. 744 at 16.) Plaintiffs ignore the fact that, throughout this MDL, Plaintiffs have commonly and interchangeably referred to surgical site infections and prosthetic joint infections. Furthermore, Plaintiffs' experts themselves refer to various terms in their reports. For example, Plaintiffs' expert Yadin David states, "[The Bair Hugger's system's] design and marketing were unreasonably dangerous because the devices are more likely than not contributing to infections during orthopedic implant surgeries." (Zimmerman Decl., Yadin David Rept., PXA, ECF No. 316 at 1.) Dr. Koenigshofer states, "In summary, I believe that use of the Bair Hugger will adversely affect the air quality in the OR and at the patient. This will place the patient at increased risk of contracting an HAI [hospital associated infection]." (Goss Decl., DX35, Daniel Koenigshofer Rept., ECF No. 829 at 163.) Dr. Jarvis states, "For a SSI/PJI to occur, contamination of the wound must occur." (Decl. of Benjamin W. Hulse in Supp. of Defs.' Mot. to Exclude Pls.' General Causation Medical Experts, "Hulse Decl. Sept. 12, 2017," DX4, ECF No. 751-1 at 159.) Dr. Lampotang is a rebuttal expert, and is pointing out the flaws in Plaintiffs' experts' opinions, using the same

language that Plaintiffs' experts use. (DX2, Lampotang Rept. at 6.) As such, his testimony is admissible.

E. Dr. Lampotang's Opinion Regarding the Numerous Potential Causes/Risk Factors of Surgical Site Infections.

Plaintiffs argue that Dr. Lampotang's list of potential causes of surgical site infections is not an actual opinion, not unique, acknowledged by both Plaintiffs' and Defendants' experts, and is unlikely to assist a jury. (ECF No. 744 at 17.) Again, Plaintiffs mischaracterize Dr. Lampotang's opinion. He does, in fact, state an opinion, and even if his opinion overlaps that of other experts, it is still admissible because an overlap or duplication of expert opinions is insufficient to justify exclusion of all or portions of the expert reports. *In re Nat'l Hockey League Players' Concussion Injury Litig.*, 2017 WL 3142399, at *8 (allowing multiple defense experts to address similar topics and subject matters because each expert's unique area of expertise and approach to the issue does not render their opinion cumulative).

F. Dr. Lampotang's Opinion on Sources of Dust, Heat, and Gas Outflows in the OR.

Plaintiffs argue that Dr. Lampotang's list of sources of dust, heat, and gas outflows in the OR is inconsistent with his testimony. (ECF No. 744 at 17-18.) Plaintiffs misread Dr. Lampotang's report. In the first sentence of the report, Dr. Lampotang states, "There are multiple sources of gas, *beyond* a forced air warming blanket, in the operating room including but not limited to those listed below." (DX2, Lampotang Rept. at 9) (emphasis added). There is nothing inconsistent with testifying that the Bair Hugger blows air and then providing a list of devices, in addition to the Bair Hugger, that blow air. (DX1,

Lampotang Dep. at 174:23-177:8.) Plaintiffs also argue that Dr. Lampotang has no independent source for this list. (ECF No. 744 at 19.) Plaintiffs ignore Dr. Lampotang's 35 years' experience in anesthesia, including being a professor of anesthesiology, which would include knowledge of the operating room environment where anesthesia is administered. (DX2, Lampotang Rept. at 2, 4.)

Plaintiffs also argue that Dr. Lampotang's incorrect cite to a figure of 500 watts for heat dissipation from a forced air warming device demonstrates a lack of intellectual rigor. (ECF No. 744 at 19.) Once again, Plaintiffs mischaracterize Dr. Lampotang's deposition testimony. During questioning, Dr. Lampotang admitted it was a typographical error, and if the actual document was placed in front of him, he could provide clarification:

> A. Because it just has a number, I cannot tell you one way or another. So if you produce the actual document I may be able to tell you whether it's – it too, is correct.
>
> Q. Well I can represent to you that one of the questions I had was why were you citing to this, because it doesn't support what –
>
> A. Then it's a -- it's a typographical error.
>
> Q. Okay.

(DX1, Lampotang Dep. at 184:1-9.)

Plaintiffs failed to produce the document during his deposition.

G. Dr. Lampotang's Discussion of the CDC Guidelines.

Plaintiffs argue that Dr. Lampotang's discussion and reliance on the 2017 CDC Guidelines is unreliable because the Guidelines do not actually address forced-air warming. (ECF No. 744 at 19-20.) Plaintiffs attempt to oversimplify the point Dr. Lampotang is

highlighting. The particular Guideline recommends to "maintain perioperative normothermia." (DX2, Lampotang Rept. at 11.) Even if the Guidelines do not name the Bair Hugger, the Bair Hugger is implicated because forced-air warming devices such as the Bair Hugger are intended to maintain normothermia.[5] (*Id.*) As such, Dr. Lampotang's reliance on the 2017 CDC Guidelines is not misplaced.

H. Dr. Lampotang's Review of Alternative Designs.

Plaintiffs argue that Dr. Lampotang does not explain why using conductive technology is not an alternative design. (ECF No. 744 at 20.) Plaintiffs simply argue that because Dr. Lampotang did no testing or includes no citations to studies, his work does not exhibit the same intellectual rigor as that of an expert in the field. (ECF No. 744 at 21.) Plaintiffs' argument is irrelevant because this Court has determined that VitaHeat's UB3 device (a conductive patient warming system) and the Bair Hugger forced-air warming device use "fundamentally different types of technology," and Plaintiffs were not entitled to discovery regarding VitaHeat's UB3 because it was not relevant. (*See* Order Sustaining the VitaHeat Relevancy Objection, ECF No. 249 at 2; and the Order Denying Plaintiffs' Objection to the Magistrate Judge Order and Affirming the Order Regarding VitaHeat, ECF No. 304 at 2.) Dr. Lampotang reviewed both Orders. (DX2, Lampotang Rept., Materials Considered.)

[5] *See* DX4, 3M Bair Hugger Warming Blankets Instructions For Use. The FDA approved Indications For Use of the Bair Hugger warming blankets, state in part, that "The 3M™ Bair Hugger™ Temperature Management System is intended to prevent and treat hypothermia."

I. Dr. Lampotang's Review of Fire in the Bugger Hugger (As Described in 2017 Moon et al., Forced Air Warming Device Failure in Smoke and Soot on a Surgical Patient).[6]

Plaintiffs argue that Dr. Lampotang's opinions regarding the Moon et al. study are unsupported assumptions that lack intellectual rigor and should be excluded. (ECF No. 744 at 22.) Again, Plaintiffs mischaracterize Dr. Lampotang's opinions. He provides support for his opinions by explaining the size of soot particles and also cites to Plaintiffs' expert Daniel Koenigshofer's report and then provides the website url to which he referred. (DX2, Lampotang Rept. at 14-15.) Even though Plaintiffs may not agree with Dr. Lampotang's review, as a rebuttal expert he is allowed to further explain and/or critique the opinions of Plaintiffs' experts, as he has done here. *Aviva Sports, Inc.*, 829 F. Supp. 2d at 835. *See also In re Mirena IUD Products Liability Litigation*, 169 F. Supp. 3d 396, 419–421 (S.D.N.Y. 2016) (citing *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 563 (S.D.N.Y. 2004) (admitting rebuttal experts' opinions that included cites to scientific literature to support their claims).

III. DR. LAMPOTANG'S OPINIONS AND TESTIMONY ARE ALSO ADMISSIBLE UNDER MINNESOTA LAW.

Minn. R. Evid. 702 states that a qualified expert's opinions and testimony are admissible if they have both: (1) foundational reliability, and (2) general acceptance in the relevant scientific community. *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). *See also McDonough v. Allina Health Sys.*, 685 N.W.2d 688, 696 (Minn. App. 2004)

[6] *See* DX5, Moon T., et al., Forced Air Warming Device Failure Resulting in Smoke and Soot on a Surgical Patient. Open Access J Surg. 2017; 4(1): 555627. DOI: 10.19080/OAJS.2017.04.555627.

(affirming the district court's determination that plaintiff's expert's general causation theory is not generally accepted). As detailed above, Dr. Lampotang's literature review of relevant materials was foundationally reliable, and his conclusion that there is no evidence that the Bair Hugger causes or increases the risk of surgical site infections is generally accepted in the scientific and medical communities. His opinions and testimony are thus admissible.

CONCLUSION

Fed. R. Evid. 702 and 703, Minn. R. Evid. 702, and controlling case law require the admission of Dr. Samsun Lampotang's opinions and testimony. Dr. Lampotang is indisputably qualified, and his opinions meet the criteria of relevancy, reliability, and usefulness. The Court should deny Plaintiffs' Motion to Exclude.

Dated: October 3, 2017

Respectfully submitted,

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